

## Subpart A—General Provisions

### § 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation specifications under part C of title XI of the Act, section 264 of Public Law 104–191, and section 13402 of Public Law 111–5.

[74 FR 42767, Aug. 24, 2009]

### § 164.103 Definitions.

As used in this part, the following terms have the following meanings:

*Common control* exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

*Common ownership* exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

*Covered functions* means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

*Health care component* means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with § 164.105(a)(2)(iii)(C).

*Hybrid entity* means a single legal entity:

- (1) That is a covered entity;
- (2) Whose business activities include both covered and non-covered functions; and
- (3) That designates health care components in accordance with paragraph § 164.105(a)(2)(iii)(C).

*Law enforcement official* means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

- (1) Investigate or conduct an official inquiry into a potential violation of law; or
- (2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

*Plan sponsor* is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

*Required by law* means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

[68 FR 8374, Feb. 20, 2003, as amended at 74 FR 42767, Aug. 24, 2009]

### § 164.104 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this part apply to the following entities:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, or other than as a business associate of a covered entity, the clearinghouse must comply with § 164.105 relating to organizational requirements for covered entities, including the designation of health care components of a covered entity.

[68 FR 8375, Feb. 20, 2003]

### § 164.105 Organizational requirements.

(a)(1) *Standard: Health care component.* If a covered entity is a hybrid entity, the requirements of subparts C and E of this part, other than the requirements of this section, § 164.314, and § 164.504, apply only to the health care component(s) of the entity, as specified in this section.